SUPPORT FOR THE AMENDMENTS

Applicant has amended Claim 1 for clarity and to incorporate the limitations of Claim 3. Accordingly, support for amended Claim 1 can be found in Claims 1 and 3, as originally filed. Claims 2, 4, 5, and 7-11 have been amended for clarity and to properly depend from amended Claim 1. Accordingly, support for amended Claims 2, 4, 5, and 7-11 can be found in the same claims, as originally filed. Claim 15 has been amended for clarity and to incorporate the limitations of Claims 3 and 16. Support for amended Claim 15 can be found in Claims 3, 15 and 16, as originally filed.

No new matter has been added. Claims 1, 2, 4, 5, 7-11, and 15 remain active in this application.

REMARKS/ARGUMENTS

Present Claims 1, 2, 4, 5, and 7-11 relate to methods for measuring quantitatively or qualitatively an analyte in a whole blood sample, comprising:

forming a reaction system by adding to the whole blood sample a first substance which is immobilized on a solid carrier and specifically binds to an analyte contained in the whole blood sample and a second substance which specifically binds to the analyte to allow the analyte to react with the first and second substances to form a complex of first substance-analyte-second substance,

separating the complex, and

detecting the complex to measure quantitatively or qualitatively the analyte in the complex,

wherein said reaction system comprises detergent in a concentration range of 0.5 to 5% so that hemolysis is prevented.

Present Claim 15 relates to reagent kits for measuring an analyte in a whole blood sample, which comprises a first substance which is immobilizd on a solid carrier and specifically binds to the analyte, a second substance which specifically binds to the analyte and a whole blood treatment solution which comprises detergent and is adjusted so that detergent concentration is 0.5 to 5% when the solution is added to the whole blood sample.

The inventor has discovered that the presently claimed methods and reagent kits are particularly useful for measuring quantitatively or qualitatively an analyte in a whole blood sample. The cited references contain no disclosure or suggestion of the presently claimed methods and reagent kits. Accordingly, these references cannot affect the patentability of the present claims.

The rejection of Claims 1-11 under 35 U.S.C. § 102(e) in view of Hoshino et al; the rejection of Claims 1, 2, 4, 5, and 7-11 under 35 U.S.C. § 102(b) in view of Watkins et al; and the rejection of Claims 1-11, 15, and 16 under 35 U.S.C. § 102(b) in view of Ullman et al are respectively traversed.

As the Examiner will note present Claim 1 has been amended to recite that the reaction system comprises detergent in the concentration range of 0.5-5% so that hemolysis is prevented.

Moreover, as for the anticipation rejections in view of Hoshino et al. and Watkins et al., it is noted that in the presently claimed methods, the reaction between an analyte in the whole blood sample, the first substance immobilized to a solid carrier, and the second substance is performed in the presence of 0.5-5% of detergent. In contrast, in the methods disclosed in Hoshino et al. and Watkins et al., the reaction between a capture antibody immobilzed on a magnetic particle, an analyte, and a labelled antibody is not performed in the presence of detergent. Rather, detergent is merely contained in a washing solution for

washing complexes of the capture antibody-analyte-labelled antibody which are formed through the reaction.

Therefore, the presently claimed method is clearly not disclosed in Hoshino et al. or Watkins et al.

As for the rejection of Claims 1-11 for being anticipated by Ullman et al., it is noted that under the conditions of the presently claimed methods, in which the reaction between an analyte in the whole blood sample, a first substance immobilized on a solid carrier, and a second substance is performed in the presence of 0.5-5% of detergent, hemolysis in the whole blood sample can be avoided, and therefore, any adverse effects caused by hemolysis on the reaction process and successive processes can be avoided. That is, by employing the presently claimed method, sensitive and accurate analysis of an analyte in a whole blood sample can be achieved.

In contrast, Ullman et al. discloses adding detergents in their assay method, but they do not disclose the concentration of the detergents or the hemolysis-prevention effect of the detergents. Although in the Office Action it is asserted that Ullman et al. discloses that the concentration of the detergent is about 0.01-1% by weight (column 12, lines 21-29, column 14, lines 46-54, and column 18, lines 63-66), the concentration shown in column 14, lines 46-54 is not the concentration of a detergent, but the concentration of a "non-specific protein material" such as BSA and BGG.

Accordingly, the presently claimed method is not anticipated by Ullman et al.

As for the rejections of claims 15 and 16 as being anticipated by Ullman et al., Claim 15 has been amended to incorporate therein the subject matter of Claim 16 and also to recite that the whole blood treatment solution contains detergent and is adjusted so that detergent concentration is 0.5-5% when the solution is added to the whole blood sample. Thus, Claim

15 is patentable over Ullman et al. for the same reasons that the method claims are patentable over this reference.

Accordingly, these rejections are improper and should be withdrawn.

The rejection of Claims 1-11, 15, and 16 under 35 U.S.C. § 112, second paragraph, has been obviated by appropriate amendment. As the Examiner will note, the claims have been amended such that they are free of the criticisms outlined on pages 2-8 of the Office Action. Thus, the rejection is no longer tenable and should be withdrawn.

Applicant submits that the present application is now ready for examination on the merits, and early notification of such action is earnestly solicited.

Respectfully submitted,

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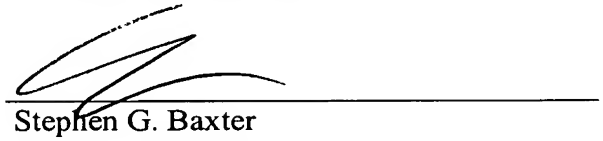

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